



PTO/SB/08A (10-01)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

1 of 14

<i>Complete if Known</i>	
Application Number	10/687,996
Filing Date	October 17, 2003
First Named Inventor	Lothar Steidler
Group Art Unit	1652
Examiner Name	Rebecca E. Prouty
Attorney Docket Number	2887-6096US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US - Provisional 60/353,923	01/31/2002	Chen	
		US - Provisional 60/353,964	01/31/2002	Chen	
		US - Provisional 60/353,885	01/31/2002	Chen	
		US - Provisional 60/401,465	08/05/2002	Chen	
		US - 2001/0006642	07/2001	Steidler et al.	
		US - 2002/0019043	02/2002	Steidler et al.	
		US - 2003/0202991	10/2003	Steidler et al.	
		US - 2003/0203472	10/2003	Portnoy et al.	
		US - 2004/0043003 A1	03/2004	Chen et al.	
		US - 4,100,495	07/11/1978	Luvison et al.	
		US - 5,032,510	07/1991	Kovacevic et al.	
		US - 5,149,532	09/1992	Brunell	
		US - 5,240,705	08/1993	Jacobs	
		US - 5,330,753	07/1994	Mekalanos et al.	

FOREIGN PATENT DOCUMENTS

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		EP 0 176 320	04/1986	Eli Lilly and Company		
		EP 0 449 770	10/1991	Ciba-Geigy AG		
		EP 0 450 176	10-09-1991	Bayer AG		
		WO 88/06626	09-07-1988	Whitehead Institute for Biomedical Research		
		WO 91/06654	05/1991	Cedars-Sinai Medical Center		
		WO 93/17117	09/1993	Lynxvale Limited		
		WO 95/03418	02/1995	Beth Israel Hospital Association: Whitehead Institute for Biomedical Research		

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		US - 5,364,774	11/1994	Muir et al.	
		US - 5,401,642	03/1995	Fiers et al.	
		US - 5,401,658	03/1995	Fiers et al.	
		US - 5,417,986	05/1995	Reid et al.	
		US - 5,455,034	10/1995	Nagaraja et al.	
		US - 5,504,005	04/1996	Bloom et al.	
		US - 5,547,664	08/1996	Charles et al.	
		US - 5,559,007	09/1996	Suri et al.	
		US - 5,591,632	01/1997	O'Donnell et al.	
		US - 5,733,540	03/1998	Lee	
		US - 5,824,538	10/1998	Branstrom et al.	
		US - 5,837,409	11/1998	Israelsen et al.	
		US - 6,100,388	08/2000	Casas et al.	
		US - 6,130,082	10/2000	Majarian et al.	
		US - 6,190,662	02/2001	Steidler et al.	
		US - 6,190,669	02/2001	Noriega et al.	
		US - 6,221,648	04/2001	Le Page et al.	
		US - 6,261,561	07/2001	Stewart et al.	
		US - 6,262,119 B1	7/2001	Ferrante et al.	

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		WO 96/32487 A1	10-17-1996	Nederlandse Organisatie		
		WO 03/096979 A	11-27-2003	Univ Leland Stanford Junior		
		WO 2004/046346	06-03-2004	VIB VZW and Universiteit Gent		
		WO 2004/045392 A	06-03-2004	Univ Leland Stanford Junior		
		WO 2007/063075 A	06-07-2007	Actogenix NV		
		WO 2008/090223 A2	07-31-2008	Actogenix N.V.		

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		ANDERSON, Human gene therapy, 1998, Nature, Vol. 392.		
		ARSLANOGLU et al., 1998, Biotechnology Letters, pp. 917-21, Vol. 20.		
		BAMBA et al., Gastroenterol J., 1993, pp. 511-17, Vol. 28, No. 4.		
		BARBARA et al., interleukin 10 gene transfer prevents experimental colitis in rats, 2000, GUT, pp. 344-349, Vol. 46.		
		BELLINI et al., Production processes of recombinant IL-1beta from bacillus subtilis: comparison between intracellular and exocellular expression, 1991, Journal of Biotechnology, pp. 177-192, Vol. 18.		
		BERMUDEZ-HUMARAN et al., J. Medical Microbiology, 2004, 53:427-433.		
		BIJLSMA et al., TRENDS in Microbiology, 2003, 11:8:359-366.		
		BILLMAN-JACOBÉ, Current Opinion in Biotechnology, 1996, 7:500-504.		
		BLAST, Basic Local Alignment Search Tool, visited 7/7/2009, < http://blast.ncbi.nlm.nih.gov/Blast.cgi >.		
		BOJOVIC et al., Applied & Environ. Microbiol., 57/2:385-388 (1991).		
		BRETT et al., Eur. J. Immunol., 23:1608-1614 (1993).		

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		CHEN et al., FEMS Microbiology Letters, 2003, 229:111-117.	
		CLAVERYS et al., Gene, 1995, 164:123-128.	
		Curtiss Tables III, IV and V, from U.S. Patent 4,888,170.	
		Cytokines Final Brochure for Cytokine Therapies, The Food and Drug Administration and The New York Academy of Sciences, held on March 26-27, 2009.	
		DARJI et al., J. Biotechnology, 1995, 43:205-212.	
		Designing bacteria and white cells to deliver drugs to the gut, The Lancet, September 20, 2003, www.thelancet.com, Vol. 362, p. 964.	
		EDWARDS et al., Infection & Immunity, 60/6:2514-2521 (1992).	
		EIZAGUIRRE et al., Abstract, Effect of Growth Hormone, Epidermal Growth Factor, and Insulin and Bacterial Translocation in Experimental Short Bowel Syndrome, Journal of Pediatric Surgery, 2000, pp. 692-695, Vol. 35, No. 5.	
		ELLIOTT et al., Bacterial colonization and healing of gastric ulcers: the effects of epidermal growth factor. Am. J. Physiol. Gastrointest. Liver Physiol., 2000, pp. G105-G112, Vol. 278.	
		English translation of the Japanese Office Action dated April 7, 2009.	
		FARRELL et al., FEMS Microbiology Letters, 1995, 130:81-85.	

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		FIGLER et al., Archives Biochemistry and Biophysics, 2000, 376:1:34-46.		
		FISCHETTI et al., Current Opinion in Biotechnology, October 1993, 4/5:603-610.		
		FU et al., "Development of a chromosome-plasmid balanced lethal system for <i>Lactobacillus acidophilus</i> with thyA gene as selective marker," Microbiol. Immunol., 2000, pp. 551-556, Vol. 44, No. 7.		
		GASSON, Abstract, "In vivo genetic systems in lactic acid bacteria," FEMS Microbiol., 1990, Rev. 87:43-60.		
		GOTZ, J. Applied Bacteriology Symposium Supplement, 1990, 49S-53S.		
		GUTIERREZ ET AL., Appl. Microbiol. Biotechnol., 2006, 72/1:41-51.		
		HANSSON et al., J. Bacteriology, July 1992, 174/13:4239-4245.		
		HARDIN et al., Gut, 1999, pp. 26-32, Vol. 44.		
		HAZEBROUCK et al., Applied and Environmental Microbiology, December 2006, 72/12:7460-7467.		
		HEATH et al., Abstract, Cytokines as immunological adjuvants, Vaccine, 1992, pp. 427-34, Vol. 10, No. 7.		
		HEGEDUS et al., Gene, 1998, 207:241-249.		

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		HERFARTH et al., Interleukin 10 suppresses experimental chronic, granulomatous inflammation induced by bacterial cell wall polymers, 1996. GUT, pp. 836-845, Vol. 39.		
		HOLMES et al., Infection & Immunity, 66/10:4633-4639 (1998).		
		HUIBREGTSE et al., Abstract, Induction of Antigen-specific Oral Tolerance by Genetically Modified Lactococcus Lactis Delivering DQ8-specific Immunodominant Gliadin Epitopes to Gluten-sensitized Class II Transgenic Mice, Clinical Immunology, January 1, 2007, pp. S53-S54, Vol. 123.		
		IWAKI et al., Infection Immunity, 58/9:2929-2934 (1990).		
		JANSSEN et al., Microbial Pathogenesis, 1995, 19:193-201.		
		JEONG et al., Food Microbiology, 2006, 23:82-89.		
		KINGMAN, Trial Tests If Modified Bacteria Can Deliver to Gut Mucosa, Nature Biotechnology, June 15, 2003, online.		
		KITCHENER, Prisons without bars, Nature Reviews, Genetics, August 2003, p. 577, Vol. 4.		
		KOIVULA et al., Isolation and Characterization of Lactococcus lactis subsp. lactis Promoters, Applied and Environmental Microbiology, Feb. 1991, pp. 333-340, Vol. 57, No. 2.		
		KONG et al., Secretion of Human Interleukin 2 by Recombinant Mycobacterium bovis BCG, Infection and Immunity, Mar. 1995, pp. 799-803, Vol. 63, No. 3.		

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		KORELITZ et al., Immunosuppressive therapy of inflammatory bowel disease: A historical perspective.		
		KRUISSELBRINK et al., Recombinant Lactobacillus Plantarum Inhibits Ouse Dust Mite-Specific T-Cell Responses, Clinical and Experimental Immunology. October 1, 2001, pp. 2-08, Vol. 126, No. 1.		
		KUBY, Cytokine receptors. 1994, Immunology. pp. 304-306.		
		KURAHAYASHI et al., Effects of EGF administration in the intestinal adaptation in the rat after massive intestinal resection, Diagnostics and New Medicaments. 1991, pp. 1691-701, Vol. 28, No. 9.		
		LEACH et al., The role of IL-10 in inflammatory bowel disease: "Of mice and men," 1999, Toxicologic Pathology, pp. 123-133.		
		LEENHOUTS et al., Applied and Environmental Microbiology, December 1998, 64/12:4736-4742.		
		LEENHOUTS et al., Applied and Environmental Microbiology, September 1991, 57/9:2568-2575.		
		LEENHOUTS et al., J. Bacteriology. August 1991, 173-15:4794-4798.		
		LEONG et al., Selective Induction of Immune Responses by Cytokines Coexpressed in Recombinant Fowlpox Virus, Journal of Virology, Dec. 1994, pp. 8125-30, Vol. 68, No. 12.		
		LIU et al., J. Applied Microbiology, 2005, 98:127-135.		

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		MAASSEN et al., Abstract, Reduced experimental autoimmune encephalomyelitis after intranasal and oral administration of recombinant lactobacilli expressing myelin antigens, Vaccine, December 1, 2003, pp. 4685-93, Vol. 21, No. 32.		
		MAYER et al., Abstract, Therapeutic potential of oral tolerance, Nature Reviews Immunology, June 2004, pp. 407-19, Vol. 4, No. 6.		
		MCCLUSKIE et al., Route and method of delivery of DNA vaccine influence immune responses in mice and non-human primates, 1999, Molecular Medicine, pp. 287-300, Vol. 5.		
		Merriam-Webster's Collegiate Dictionary, Tenth Edition, Springfield, Massachusetts, USA, 2001, p. 922.		
		MOTAMEDI et al., Gene, 1995, 160:25-31.		
		NORTON et al., FEMS Immunology and Medical Microbiology, 1996, 14:167-177.		
		NORTON et al., FEMS Microbiology Letters, 1994, 120/3:249-256.		
		NORTON et al., Progress in the Development of Lactococcus Lactis as a Recombinant Mucosal Vaccine Delivery System, Folia Microbiologica, January 1, 1995, pp. 225-30, Vol. 40, No. 3.		
		NORTON et al., Vaccine, 1997, 15(6/7):616-619.		
		NOTTEBROCK et al., Thymidine Concentrations in Serum and Urine of Different Animal Species and Man, Biochemical Pharmacology, 1977, pp. 2175-79, Vol. 26, Pergamon Press, Great Britain.		
		OGGIONI et al., Gene, 1996, 169:85-90.		

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		OGGIONI et al., Vaccine, 1995, 13:8:775-779.		
		PACCEZ et al., Vaccine, 2007, 24:4671-4680.		
		PAGE et al., Innovations in oral gene delivery: challenges and potentials, 2001, DDT, pp. 92-101, Vol. 6.		
		PAPADAKIS et al., Role of cytokine in the pathogenesis of inflammatory bowel disease, 2000, Annu. Rev. Med., Vol. 51, pp. 289-298.		
		PCT International Preliminary Examination Report, PCT/EP02/04942, dated September 16, 2003, 5 pages.		
		PCT International Search Report, PCT/EP02/04942, dated January 13, 2003, 2 pages.		
		PCT International Search Report, PCT/EP2005/052296, dated September 5, 2005.		
		PCT International Search Report, PCT/EP2008/050900, dated November 24, 2008.		
		PLATTEEUW et al., Applied and Environmental Microbiology, 1996, 62/3:1008-1013.		
		POUWELS et al., Genetics of lactobacilli: plasmids and gene expression, 1993, Antonie Van Leeuwenhoek, pp. 85-107, Vol. 64.		
		POUWELS et al., International J. Food Microbiology, 1998, 41:155-167.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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of

14

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Application Number	10/687,996
Filing Date	October 17, 2003
First Named Inventor	Lothar Steidler
Group Art Unit	1652
Examiner Name	Rebecca E. Prouty
Attorney Docket Number	2887-6096US

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		POUWELS et al., J. Biotechnology, 1996, 44:183-192.	
		POZZI et al., Abstract, Research in Microbiology, 1990, 141/6:659-670.	
		POZZI et al., Abstract, Research in Microbiology, 1992, 143/5:449-457.	
		POZZI et al., Infection and Immunity, May 1992, 60/5:1902-1907.	
		RAMASANY et al., Vaccine, 2006, 24:3900-08.	
		RAO et al., Eur. J. Pharmacol., 1996, pp. 209-12, Vol. 303, No. 3.	
		RAPOPORT, Current Opinion in Biotechnology, 1:21-27 (1990).	
		REVIRIEGO et al., International Dairy Journal, 2007, 17:574-577.	
		ROBINSON et al., Nature Biotechnology, 1997, 15:653-57.	
		RODRIGUEZ et al., International J. Food Microbiology, 2003, 80:101-116.	

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		SALZET, Michel, "Leech Thrombin Inhibitors," Current Pharmaceutical Design, 2002, pp. 493-503, Vol. 8.	
		SAMUELSON et al., J. Bacteriology, March 1995, 177/6:1470-1476.	
		SASAKI et al., "thyA as a Selection Marker in Construction of Food-Grade Host-Vector and Integration Systems for Streptococcus thermophilus," Applied and Environmental Microbiology, March 2004, pp. 1858-1864, Vol. 70, No. 3.	
		SCOTT et al., Abstract, FEMS Microbiology Ecology, August 1998, 26/3:219-230.	
		SHAM et al., Abstract, Epidermal Growth Factor Improves Nutritional Outcome in a Rat Model of Short Bowel Syndrome, Journal of Pediatric Surgery, 2002, pp. 765-769, Vol. 37, No. 5.	
		SIBAKOV et al., Applied & Environ. Microbiol., 57/2:341-348 (1991).	
		SLOS et al., FEMS Microbiology Letters, 1998, 169:29-36.	
		STEIDLER et al., "Secretion of Biologically Active Murine Interleukin-2 by Lactococcus lactis subsp. lactis, Appl. Environ. Microbiol., 1995, 61:1627-1629.	
		STEIDLER et al., J. Bacteriol. 175/23:7639-7643 (1993).	
		STEIDLER et al., Mucosal Delivery of Murine Interleukin-2 (IL-2) and IL-6 by recombinant Strains of Lactococcus lactis Coexpressing Antigen and Cytokine, Infection and Immunity, 1998, pp. 3183-3189 Vol. 66, No. 7:	

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Sheet	13	of	14	First Named Inventor	Lothar Steidler
				Group Art Unit	1652
				Examiner Name	Rebecca E. Prouty
				Attorney Docket Number	2887-6096US

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		STEIDLER et al., NATO ASI Series Vol. H98, pp. 63-79 (1996).	
		STEIDLER et al.. Therapeutic drug delivery by genetically modified <i>Lactococcus lactis</i> , Annals of the New York Academy of Sciences. 2006. pp. 176-86.	
		STERN, et al., Abstract. Microscopy Research and Technique, 2000, pp. 138-148, Vol. 51.	
		TARGAN et al., Clarifying the causes of Croh's. 1995, Nature Medicine, pp. 1241-43, Vol. 1.	
		THOMPSON et al., Plasmid, 2001, 46:188-201.	
		Un probiotique genetiquement modifie, Nature Biotechnology, on line, 15 June 2003.	
		VAN DE GUCHTE et al.. Applied and Environmental Microbiology, January 1989, 55(1):224-228.	
		VAN DE GUCHTE et al.. Heterologous Gene Expression in <i>Lactococcus lactis</i> subsp. <i>lactis</i> : Synthesis, Secretion, and Processing of the <i>Bacillus subtilis</i> Neutral Protease, Applied and Environmental Microbiology, Sept. 1990, p. 2606-2611. Vol. 56, No. 9.	
		VAN MALLAERT et al., Med. Fac. Landbouww. Rijksuniv. Gent., 1989, 54(4b):1477-1485.	
		VERMA et al., Gene therapy—promises: problems and prospects, 1997, Nature, pp. 239-242, Vol. 389.	

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Attorney Docket Number	2887-6096IJS

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		WATERFIELD et al., Gene, 1995, 165:9-15.	
		WELLS et al., Applied & Environ. Microbiol., 59/11:3954-3959 (1993).	
		WELLS et al., International Dairy Journal, 1995, 5:1071-1079.	
		WELLS et al., Lactic acid bacteria as vaccine delivery vehicles, Antonie van Leeuwenhoek 70:317-330 (1996).	
		WELLS et al., Molecular Microbiol. 8/6:1155-1162 (1993).	
		WIEDERMANN, Abstract. Prophylaxis and therapy of allergy by mucosal tolerance induction with recombinant allergens or allergen constructs, Current Drug Targets, Inflammation and Allergy, October 1, 2005, pp. 577-83, Vol. 4, No. 5, Bentham Science Publishers.	
		WILLIAMS et al., Plasmid, 2002, 47:241-245.	
		WILLIS, Bacterial drug delivery, Newsinbrief, online (after June 15, 2003).	
		Notice of Allowance for Application No. 11/018,188 dated April 8, 2009.	
		Office Action for Application No. 11/127,921 dated March 10, 2009.	

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